REMARKS

Initially, the Examiner is respectfully requested to list the reference, Nies et al (US 5,650,108), on a Notice of References Cited, Form PTO-892.

In the present Amendment, claims 2-3 and 12 have been cancelled without prejudice or disclaimer. Applicants reserve the right to pursue the cancelled subject matter in the future. Claim 4 has been amended to depend from claim 1. Section 112 support for the amendment is found, for example, at page 3, lines 14-17 of the specification. Claims 13 and 15 have been amended to recite "bone morphogenic protein" instead of "BMP." Section 112 support for the amendment is found, for example, at page 15, lines 23-24 of the specification. Claims 9 and 10 have been amended to recite "~~the~~ a polymer prepared *in situ*." In addition, claims 9, 10, 11, 16, 17 and 42 have been amended to recite "the particulate polymer portion" in place of "the polymer particles portion," so that the antecedent basis is clearer. No new matter has been added. Withdrawn claim 25 is amended to correct a typographical error.

Upon entry of the Amendment, claims 1, 4-11 and 13-42 will be pending, of which claims 18-41 are withdrawn from consideration.

Response to Claim Objection

In paragraph 2 at page 2 of the Action, claims 13 and 15 are objected to because, per the Examiner, the recited acronym (BMP) needs to be defined in the claims.

As noted, claims 13 and 15 have been amended to address the Examiner's concern. Accordingly, withdrawal of the objection to claims 13 and 15 is requested.

Response to §112 Rejection

In paragraph 4 at page 2 of the Action, claims 9, 10, 11, 12 and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Specifically, as to **claims 9-11 and 42**, the Examiner contends that the limitation "within the polymer" in the recitation "... compared to the concentration of the organoiodine within the polymer prepared *in situ* from the monomer during the use" lacks sufficient antecedent basis.

As to **claim 12**, the Examiner contends that claim 12 recites that the organoiodine compound is a "cross-linking agent" in line 3 which renders the claim indefinite, because the organoiodine compound referred to in claim 1 is "non-polymerizable."

As noted, the claims have been amended to address the Examiner's concern and claim 12 has been cancelled. Accordingly, withdrawal of the § 112 rejection is requested.

Response to §103 Rejections

In paragraph 6 at page 4 of the Action, claims 1, 4, 5, 6, 16 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lidgren (US 6,586,009) in view of Koole (US 6,040,408).

In paragraph 9 at page 7 of the Action, claims 6, 7, 8, 12 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lidgren, and further in view of Nies et al (US 5,650,108).

In paragraph 10 at page 8 of the Action, claims 13 and 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lidgren, and further in view of Lautenschlafer et al (US 5,902,839).

Applicants submit that the above three rejections should be withdrawn because Lidgren, Koole, Nies et al and Lautenschlafer et al do not disclose or render obvious the present invention, either alone or in combination.

Lidgren is cited as teaching a bone cement composition comprising a liquid component of polymerizable substances and a powder component containing acrylic polymer particles,

polymethylmethacrylate or copolymers containing polymethylmethacrylate and an X-ray contrast medium, e.g., iohexol (claim 1 and Example 1 at col. 3, line 9).

The Examiner acknowledges that Lidgren is silent on liquid component having organoiodine component.

Koole is cited as teaching a polymer of a monomer molecule that contains covalently-bound iodine (col. 1, lines 28-30), such as iodine-containing substituent [NH-CH_2-CH_2-O-C(O)-$C_6H_2I_3$] (col. 2, line 17).

The Examiner concludes that one of ordinary skill in the art would have readily combined the iodine containing polymer of Koole with the polymer powder component of Lidgren in order to achieve a bone cement composition comprising a liquid component containing a dissolved non-polymerizable organoiodine component as presently claimed.

Applicants respectfully disagree and traverse the rejection.

The Examiner believes that the bone cements described in Lidgren differ from the present invention only in that the Lidgren does not disclose a liquid portion containing an organoiodine component.

However, this is not the only difference. Lidgren discloses a composition with a particulate component comprising separate *particles* of a water-soluble non-ionic organoiodine compound and polymer. The compositions of Lidgren do not therefore contain a *dissolved* organoiodine compound, whereas present claim 1 requires that the organoiodine compound is dissolved in one of the portions. Furthermore, as the Examiner acknowledges, the compositions of Lidgren do not involve a liquid component comprising an organoiodine compound.

Neither of the features missing from Lidgren are found in Koole. Koole discloses a biomedical polymer having polymerized therein at least one monomer containing a covalently

bound iodine group, i.e., the monomers are organoiodine compounds. As the monomers of Koole contain iodine and are then polymerized, the organoiodine compounds (which are the monomers) can not be described as "non-polymerizable." Koole therefore does not disclose dissolved non-polymerizable organoiodine compounds.

As explained in the second paragraph at page 2 of the specification, agents such as iohexol and iodixanol, the preferred contrast agents of Lidgren, are known to have a negative impact on the mechanical properties of cements into which they are incorporated. The present invention provides radio-opaque bone cements with improved mechanical strength. There is no suggestion in the prior art that use of dissolved organoiodine compounds would produce bone cements with improved mechanical strength. In fact, as discussed above, even if the teachings of Lidgren and Koole were combined, the present invention would not have been achieved.

Nies et al is cited as teaching a clindamycin antibiotic compound (col. 5, line 29) which is asserted to read on a lipophilic ester antibiotic compound. Lautenschlager et al is cited as teaching a bone cement composition (abstract) with a liquid polymer component having a hydroquinone. Nies et al and Lautenschlafer et al do not make up for the deficiencies of Lidgren.

Accordingly, the present claims are not obvious and are patentable over Lidgren, Koole, Nies et al and Lautenschlafer et al, either alone or in combination.

In view of the above, reconsideration and withdrawal of the §103(a) rejections based on Lidgren, Koole, Nies et al and Lautenschlafer et al are respectfully requested.

In paragraph 7 at page 5 of the Action, claim 2 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Koole in view of Vazquez et al ("Radiopaque acrylic cements prepared with a new acrylic derivative of iodo-quinoline," Biomaterials, 1999, pp. 2047-2053).

In paragraph 8 at page 6 of the Action, claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Koole in view of Vazquez et al.

Claims 2 and 3 have been cancelled, rendering the above two rejections moot.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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